

# Factors to Consider in the Composition of an Adjudication Committee: Nuts and Bolts



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**Peter Kowey, MD, FACC, FHRS, FAHA**  
Lankenau Institute for Medical Research  
Jefferson Medical College  
Philadelphia, PA

# Disclosures

- Dr. Kowey has served on dozens of such committees over 32 years and has always worked “fee-for-service” on such projects.
- Dr. Kowey remains unconvinced as to the value of wholesale case adjudication but believes that it is useful in selected trials. The challenge is to choose appropriately.
- Dr. Kowey further believes that some committees are much better than others, most of the difference having to do with preparation and the constituency of the committee.



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# Edward R. Murrow

“A great many people think they are thinking when they are really rearranging their prejudices.”



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# Make The Case

- If there is a compelling reason to utilize an end-point committee, it needs to be explicitly stated in the charter.
- We should continue to gather data regarding the behavior of these committees in a prospective way for future considerations.



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# Hands Off

- Once a decision is made to proceed, the CEC needs to be constituted with great care and transparency.
- An experienced academic chair with full latitude regarding member selection, charter, SOPs may be the best model, but it is labor intensive.



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# The most important question: Who?

- Experienced clinicians with academic credentials
- The chair is everything
- Broad knowledge of guideline definitions that shape the charter
- Discourage fellows, retirees, professional adjudicators, and lawyer wanna be's
- Appropriate expertise for problem area but not overly narrow
- Efficient and responsive to avoid log jams
- Avoid temptation to go to the same well too often



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# Mechanics

1. Security and confidentiality are paramount
2. Independent vs group deliberation
3. Selective case discussion by phone, e mail or in person (F2F meetings are inefficient in most cases)
4. Charters are critical
  - methods and diagnostic criteria
  - immutable except in rare circumstances
  - consider standardization



# How to maximize the yield

- Excellent organization and data flow are essential
- Narratives are helpful and supplement (do not replace) source documents
- Exact methods to query sites when information is inadequate
- Rolling > retrospective review to avoid bias
- Sponsor rolls the ball and then gets out of the way of the CRO and committee
- Avoid “indeterminate” judgments
- Default to worst outcome when data are sparse (?)
- CRO flexibility to facilitate the committee’s work





# Independence

- There should be NO attempt to integrate any part of the end-point committee work in the sponsor's decision-making process
- Interim analyses deferred to DSMB and steering committees
- No participation in any aspect of data preparation or FDA interaction. Chair's presence at FDA Ad Comm meetings may be helpful for specific procedural questions



# Conclusions

- Endpoint committees are useful in carefully selected circumstances—but not all
- Intensive planning pays huge dividends
- Standardization of definitions and criteria are essential to make sense of the data
- This is the ultimate example of “the devil is in the details.”



# Erich Fromm

“The task we must set for ourselves is not to feel secure, but to be able to tolerate insecurity.”



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